IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 7 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.

In seeking to exclude certain general opinions of Dr. Daniel Elliott in this Wave 7, Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon" or "Defendants") re-hash the same arguments they asserted in Wave 3 of the MDL. Plaintiffs accordingly incorporate their Wave 3 Memorandum in Opposition to Defendants' Motion to Exclude Certain General Opinions of Daniel Elliott, M.D. (ECF No. 2952), as if fully set forth herein. Defendants otherwise raise arguments that this Court and/or others have addressed and rejected, and the Court should likewise reject them here. For the reasons previously stated in Doc. 2952 and the additional reasons set forth herein, Defendants' motion to exclude certain general opinions of Daniel Elliott, M.D., should be denied.

BACKGROUND

Dr. Elliott is a professor of urology in the section of Female Urology and Reconstructive Surgery at the Mayo Clinic Graduate School of Medicine in Rochester, New York. Rule 26 Expert Report of Dr. Daniel Elliott pertaining to TVT ("TVT Report"), Defendant's Exhibit C, at 1, 3 & Rule 26 Expert Report of Dr. Daniel Elliott pertaining to TVT-O ("TVT-O Report"),

Defendant's Exhibit D, at 1, 3. Dr. Elliott graduated in 1993 from Loma Linda University School of Medicine in California. He then completed his surgical residency in urology at the Mayo Clinic, and a one-year advanced surgical fellowship at Baylor College of Medicine in Texas, in Neurology, Urodynamics and Voiding Dysfunction. Def. Ex. C at 1. Dr. Elliott is certified by the Board of Urology and the Board of Obstetrics and Gynecology in female pelvic medicine and reconstructive surgery. *Id.*

For 15 years at the Mayo Clinic, Dr. Elliott has specialized in treating pelvic organ prolapse ("POP") and urinary incontinence in women, including managing highly complicated SUI patients and mesh-related complications. *Id.* at 1, 3. Dr. Elliott and a colleague at Mayo were the first to perform robotic sacrocolpopexy surgery for the treatment of POP, and the first to publish extensively on the subject. *Id.* at 1. Dr. Elliott has published more than 60 peer-reviewed articles and given more than 100 lectures, many of which relate to the subjects of POP and urinary incontinence, including their evaluation, treatments, surgical options and management of complications. *Id.* Dr. Elliott is an editor and/or reviewer for 15 urologic and/or gynecologic journals, and has kept abreast of medical literature on SUI treatment options. *Id.* at 4.

In developing his opinions, Dr. Elliott relied on his education, training, and experience, as well as his review of medical literature and Ethicon internal documents and the testimony of Ethicon employees. *Id.* at 2-4; Def. Ex. D at 2-4. The arguments raised by Defendants in attempting to limit Dr. Elliott's testimony either lack merit or raise issues that should be addressed on cross-examination. Defendants' motion should, accordingly, be denied.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). This aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

ARGUMENT

I. Dr. Elliott is well qualified to testify about the inadequacy of Ethicon's warnings from a clinical perspective, and should again be permitted to opine about the TVT's warnings without discussing FDA requirements.

Ethicon seeks to limit Dr. Elliott from testifying about whether specific risks appeared in the TVT and TVT-O IFUs and preclude him from testifying about whether or not other risks should be included in an IFU. Def. br. (ECF No. 5340) at 3. It is telling that Defendants' effort to limit Dr. Elliott's warnings opinions based on his qualifications relies on rulings as to **other experts** in this litigation. The Court has previously permitted Dr. Elliott to opine about warnings, with a small limitation. His qualifications have not changed—if anything, his

knowledge on the subject has only increased—and the Court should reiterate its prior opinion on that issue.

This Court previously addressed Dr. Elliott's own qualifications to opine as to the sufficiency of the warnings on Cook, Inc.'s Stratasis Urethral Sling product, which is indicated for the treatment of stress urinary incontinence ("SUI"). *See Watkins v. Cook Inc.*, No. 2:13-CV-20370, 2015 WL 1395773, at *1 (S.D. W. Va. Mar. 25, 2015) (discussing the nature of the product).

In addressing Dr. Elliott's qualifications to opine regarding the sufficiency of Cook's warnings, this Court wrote as follows:

> Next, Cook contends Dr. Elliott is not qualified to opine on product warnings or labels. In response, the plaintiff explains that "Dr. Elliott will not discuss defendants' warnings in a regulatory context." Instead, "Dr. Elliott's report identifies particular risks with SIS biomaterials and explains that the IFU and defendant's product literature fails to disclose these risks." I agree with the plaintiff that a urologist like Dr. Elliott is qualified to make this comparison. *See Wise v. C.R. Bard, Inc.*, No. 2:12–cv–01378, 2015 WL 521202, at *9–10 (S.D. W.Va. Feb. 7, 2015) (finding a urogynecologist qualified to opine on product labeling based on his knowledge and clinical experience); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D. W. Va. 2014) (finding a urologist qualified to opine on the risks of implanting a product and whether those risks were adequately expressed on the product's IFU). Relying on the plaintiff's assurance that Dr. Elliott's testimony will be limited to an evaluation of Cook's warnings based on his knowledge of and clinical experience with the risks of SIS products—and not on FDA requirements or regulations—Cook's motion with regard to product warnings and labeling is **DENIED.**

Watkins, 2015 WL 1395773, at *10 (record citations omitted).

Therefore, this Court held that Dr. Elliott is qualified to identify the particular risks with a product, and then explain that the IFU and the Defendants' product literature failed to disclose the risks. That prior order describes exactly what Dr. Elliott has done here.

Dr. Elliott's reports go into extensive detail regarding the complications associated with the TVT and TVT-O products that do not appear in their IFUs. TVT Report, Def. Ex. C, at 34-

37; TVT-O Report, Def. Ex. D, at 37-40. Dr. Elliott further opines that these omissions compromised the ability of physicians to adequately and appropriately consent their patients prior to the implantation of the devices. *Id.* Thus, as in *Watkins*, Dr. Elliott's warnings opinions are "limited to an evaluation of [the manufacturer's] warnings based on his knowledge of and clinical experience with the risks of [the TVT and TVT-O]—and not on FDA requirements or regulations." *Watkins*, 2015 WL 1395773, at *10. This Court, therefore, should allow Dr. Elliott to give his opinions regarding warnings, as stated in his expert reports.

II. Dr. Elliott's opinions that non-mesh repairs are safer alternatives are relevant and reliable.

A. Dr. Elliott's opinions on non-mesh repairs are relevant.

Defendants seek to preclude Dr. Elliott from testifying that non-synthetic mesh SUI repair is evidence of a safer alternative design. Plaintiffs are mindful that the Court has ruled that under West Virginia law, surgical procedures, specifically, the Burch procedure, is not evidence of an alternative, feasible design in relation to the TVT. *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942 (S.D. W.Va. 2017). However, the Court in *Mullins* did not address pubovaginal slings, which is competent evidence of an alternative design product. *See Mullins*, 236 F. Supp. 3d 940. Additionally, under Ohio law, a design defect claim considers the availability of "a practical and technically feasible alternative design *or formulation*." Ohio Rev. Code 2307.75(F) (emphasis added).[1] Defendants cite to no case that interprets this language so restrictively as to preclude consideration of non-mesh repair, whether a Burch colposuspension or an autologous sling, as an alternative design or formulation to the TVT or TVT-O. Moreover,

[1] As Defendants point out, Elliott has been designated as a general expert in two Wave 7 cases. Defendants state, without analysis, that the two cases involve West Virginia and Ohio law, respectively. Without conceding any choice of law issue, Plaintiffs address both states' law herein.

courts in other jurisdictions have concluded that proposed alternative designs involving the substitution of one material for another are proper evidence of a feasible and safer alternative design. Finally, the non-mesh repair evidence is relevant and admissible with respect to issues of risk-utility and negligence and as rebuttal.

Dr. Elliott should be permitted to testify about the pubovaginal sling category of product as an alternative, feasible design for the TVT or TVT-O, even if the Burch repair is not permitted for this purpose. Generally, pubovaginal slings use tissue from a human or animal cadaver to create the sling that is used to treat SUI. For instance, one company that produces such products is Coloplast Corp. In describing its product on its website, Coloplast writes:

> Product description: Axis dermis has omnidirectional fibers that give it consistent high tensile strength, and the network of collagen bundles interconnecting in every direction make implantation and ingrowth uniform. Axis is extracted only in large pieces from the lower back and the back of upper leg. This gives Axis consistency in quality and structure.

Coloplast: Axis, https://www.coloplast.us/Axis-en-us.aspx#section=product-description_3 (last visited March 21, 2018). As this example describes, pubovaginal slings such as allografts are alternative products to treat stress urinary incontinence, using natural material instead of synthetic polypropylene.[2]

A drug case from this Court held that a jury should decide whether the substitution of natural material for synthetic material constitutes an alternative design under West Virginia law. *See Keffer v. Wyeth*, 791 F. Supp. 2d 539, 548-50 (S.D. W. Va. 2011). In *Keffer*, the issue involved a hormonal replacement therapy drug. *Id.* at 541. The plaintiffs argued that the drug was dangerous because of the synthetic progestin in the drug, and asserted that natural material-

[2] While the *Mullins* court held that polypropylene sutures in and of themselves are not an alternative, feasible design for the TVT, there is substantial additional material involved in a pubovaginal sling, in addition to whatever is used to hold it in place, which may or may not be a polypropylene suture. *See Mullins*, 236 F. Supp. 3d at 943-44.

oral micronized progesterone-would have been a safer ingredient to use in the drug. *Id.* at 548. The defense argued that the use of a natural material created a different product altogether, and therefore could not be held up as a "safer alternative design." But the court held that the jury should decide whether substituting a natural component for a synthetic component creates an entirely different product. *Id.* at 549. The same reasoning should apply here. Dr. Elliott's opinions on pubovaginal slings support the argument that the use of polypropylene mesh is not a necessary characteristic of the product. The jury should decide whether a product made primarily from native tissue was a safer alternative to mesh products.

Further, Ohio law allows for consideration of a proposed alternative design that involves a different material than that used in the product at issue. *See, e.g., Rheinfrank v. Abbot Labs, Inc.*, 137 F. Supp. 3d 1035, 1039-40 (S.D. Ohio 2015) (concerning alternative antiepileptic drugs of entirely different formulations); *Hart v. Honeywell Int'l*, No. 1:15CV10000, 2017 WL 1235000, at *8 (N.D. Ohio Apr. 4, 2017) (Whether asbestos-free brake product was a feasible alternative design to asbestos brake product was question for jury.).

Defendants wrongly contend that its argument for excluding non-mesh repair evidence is consistent with "a general principle of product liability law." Def. br. (ECF No. 5340) at 5 n.1. In reality, there is no universal view as to what constitutes an alternative design, and the issue is typically a question for the jury. Several courts in other jurisdictions have concluded that proposed alternative designs involving the substitution of one material for another are proper evidence of a feasible and safer alternative design. *See, e.g., Collins v. Navistar, Inc.*, 155 Cal. Rptr. 3d 137, 159-60 (Cal. Ct. App. 2013) (plaintiffs were entitled to present evidence that the defendant could have made the windshields of its trucks from bilaminated "glass-plastic," rather than single-laminated glass); *Warnke v. Warner-Lambert Co.*, 799 N.Y.S.2d 666, 669 (N.Y. App.

Div. 2005) (affirming a jury verdict in favor of a plaintiff who presented evidence that the defendant could have designed its razors using a different type of plastic); *In re: Methyl Tertiary Butyl Ether ("MTBE") Prods. Liability Litig.*, 175 F. Supp. 2d 593, 624 (S.D.N.Y. 2001) (allegations that safer alternatives were available to the fuel additive the defendants included in their gasoline were sufficient to state a claim for design defect); *Barrow v. Bristol-Myers Squibb*, No. 96-689- CIV-ORL-19B, 1998 WL 812318, at *42 (M.D. Fla. Oct. 29, 1998), *aff'd sub nom. Barrow v. Bristol Meyers Squibb*, 190 F.3d 541 (11th Cir. 1999) (breast implants could be designed utilizing saline solution instead of silicone gel fillers); *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 15 (S.C. 2010) (describing as a "design alternative" a manufacturer's "decision to use one type of inferior material as a component part one year, but a superior material the following year"); *Banks v. ICI Americas, Inc.*, 264 Ga. 732, 736 n. 6 (Ga. 1994) (allowing courts to consider "the feasibility of an alternative design as well as the availability of an effective substitute for the product which meets the same need but is safer"). *See also Sisk v. Abbott Labs.*, No. 1:11CV159, 2012 WL 3155586, at *5 (W.D.N.C. June 19, 2012) (denying motion to dismiss because plaintiffs had plausibly alleged that liquid baby formula was a safer alternative to powder).

Further, whether a proposed alternative design amounts to a completely different product—rather than an "alternative design"—is often a question of fact for the jury. For instance, in *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895 (E.D. Va. 2010), the plaintiff proposed two alternative designs that she claimed would have decreased the risk of breast cancer in patients taking Prempro, the defendant's hormone therapy drug: (1) a change in the recommended dosage, and (2) the use of natural progesterone instead of synthetic progestin. *Id.* at 900. On the issue of whether these changes would create a new product, the court held that

"[t]his is, of course, typically a question of fact, not law" and called upon the jury to decide whether an alternative dosage of the defendant's drug, or the use of a natural progesterone instead of synthetic progestin, would render the defendant's drug an entirely different product. *Id.* at 900-01.[3] The same reasoning should apply here. The jury should decide whether a product made primarily from native tissue was a safer alternative to mesh products.

Defendants cite to excerpts of Dr. Elliot's prior testimony, contending that Dr. Elliott "fully agrees" that the Burch and autologous sling alternatives are not medical devices. *See* Def. br. at 5. That is misleading. Dr. Elliot testified that native material devices that treat SUI are not medical devices in the sense that they are not man-made. *See* Def. Ex. F at 25:6-11 ("Q: The cadaveric sling is not a medical device, correct? A: Well, it's – it's a device – it's a product that is purchased from the company Coloplast. So I don't think it qualifies. It's not a man-made device."). Further, in stating that there is no comparison between the TVT and these devices, Dr. Elliott was referring to their safety and complication rates long-term. *See id.* 93:14-21 ("Q: Would you like to see more long-term data on the autologous pubovaginal sling? A: Long-term studies are always going to be important. However, *when we're talking about safety and complications, it's comparing applies to oranges* because there is no medical device placed in those patients that's permanent." (emphasis added)). That is entirely consistent with his opinions in this case that these alternatives are safer than the TVT and TVT-O. Thus, Dr. Elliott should

[3] *See also Kimball ex rel. Kimball v. RJ Reynolds Tobacco Co.*, No. C03-664JLR, 2006 WL 1148506, at *3 (W.D. Wash. Apr. 26, 2006) (holding that a jury should decide whether the plaintiff's alternative cigarette designs still qualified as cigarettes); *Haglund v. Philip Morris, Inc.*, No. 012367C, 2009 WL 3839004, at *9 (Mass. Super. Oct. 20, 2009) (same); *Osorio v. One World Techs., Inc.*, 716 F. Supp. 2d 155, 157 (D. Mass. 2010) (denying defendant's motion to overturn a jury verdict where the defendant argued the plaintiff's proposed design alternative was a "categorically different product altogether" in part because the court was not persuaded that a reasonable person could come to "only one conclusion."), *aff'd* 659 F.3d 81 (1st Cir. 2011).

be permitted to testify as to why pubovaginal slings are a safer alternative product to the man-made TVT and TVT-O slings.

Additionally, Defendants do not even address several alternative issues of relevance. The non-mesh repair evidence is admissible as rebuttal to Defendants' oft-repeated contention that the TVT and/or TVT-O devices are the "gold standard" for the treatment of SUI. *See, e.g., Wiltgen v. Ethicon, Inc.*, No. 12-cv-2400, 2017 WL 4467455, at *3 (N.D. Ill. Oct. 6, 2017) (The availability of other safe and effective procedures is admissible to rebut Ethicon's contention that the TVT and similar products are the "gold standard" for treating SUI.); *Herrera-Nevarez v. Ethicon, Inc.*, No. 17C3930, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017) (holding same with respect to "TVT-O and similar products").

Dr. Elliott's opinions with respect to non-mesh alternatives are also relevant to the risk-utility analysis in a design defect claim. Federal courts in remanded mesh cases have recently held that the "availability of other safe and effective procedures (including surgical procedures) to treat the same condition is relevant and admissible to show the utility of a product" under Illinois design defect law. *Wiltgen*, 2017 WL 4467455, at *4 (citing *Herrera-Nevarez*, 2017 WL 3381718, at *7 (holding same)). Such testimony is equally relevant here, whether under West Virginia or Ohio law, as both states also use a risk-utility analysis to prove design defect. *See* Ohio Rev. Code 2307.75(A) (providing that a product is defective in design or formulation if the foreseeable risks associated with its design or formulation exceed its benefits); *Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, 2016 WL 7197441, at *4 (S.D. W. Va. Dec. 9, 2016) (discussing design defect risk-utility test under West Virginia law, which includes consideration of the potential harm of the device, the likelihood the harm would occur, and other relevant factors).

Dr. Elliott's opinions with respect to non-mesh alternatives are also relevant to a negligence claim under West Virginia law. In the product liability context, the manufacturer has a duty to use reasonable care, which means that the manufacturer must use "the amount of care in [designing] the product that a reasonably careful manufacturer … would use in similar circumstances to avoid exposing others to a foreseeable risk of harm." W. Va. Pattern Instructions § 425. A manufacturer's "duty of reasonable care requires him to recognize an unreasonable risk of harm to those who use the products as designed." *Yost v. Fuscaldo,* 408 S.E.2d 72, 76 (W. Va. 1991). In determining whether Ethicon's conduct was reasonable, a jury should consider whether there were other options on the market at the time that were safer and effective for the treatment of SUI. *See Mullins*, 236 F. Supp. 3d at 944 (acknowledging that although an alternative design is not required element of a negligence theory, it is "certainly" relevant to the manufacturer's conduct).

B. Dr. Elliott's opinions comparing the TVT devices to non-mesh repairs are reliable.

Defendants take issue with Dr. Elliott's comparison of the TVT devices to non-mesh repairs as unreliable, as they did in Wave 3. As the Court previously stated of Defendants' arguments in Wave 3, the arguments raised here "are different from previous arguments by only the very slightest of degrees." *In re: Ethicon, Inc. Pelvic Repair Liab. Litig*, MDL 2327, 2017 WL 4769665, at *1 (S.D. W. Va. July 20, 2017) (adopting Memorandum and Order (*Daubert* Motion re: Daniel Elliott, M.D.) entered on August 26, 2016, as to Wave 1 cases in the Wave 3 cases). In reality, Dr. Elliott has reviewed, analyzed and discussed all relevant scientific studies and data. He provides scientific support for this opinions, and relies on his extensive professional surgical and medical training and experience in reaching his opinions. Plaintiffs incorporate their argument on this issue as set forth in Sections I and II of Doc. 2952.

Defendants' motion should be denied on this point. Alternatively (as Defendants also alternatively argue), the Court should adopt its prior ruling from Wave 1, and reserve ruling on this topic "until further testimony may be offered and evaluated firsthand at trial." *In re: Ethicon, Inc. Pelvic Repair Liab. Litig*, MDL 2327, 2016 WL 4500768, at *4 (S.D. W. Va. Aug. 26, 2016).

III. Dr. Elliott 's opinions concerning lighter weight, larger pore mesh are reliable.

Defendants adopt its Wave 3 argument on this issue as set forth in Section II.B of Doc. 2815. In response, Plaintiffs adopt is Wave 3 arguments as set forth in Section III of Doc. 2952.

Importantly, this Court has previously held that Dr. Elliott is qualified to testify regarding mesh properties. *In re: Ethicon, Inc. Pelvic Repair Liab. Litig*, 2016 WL 4500768, at *4 (denying Defendants' motion regarding Dr. Elliott's qualifications to "offer expert testimony about alternative designs (e.g., mesh with larger pore size and less weight)"). And, federal courts in remanded Ethicon mesh cases have followed this Court's prior ruling and held that Dr. Elliott may testify regarding other synthetic mesh devices. *Wiltgen,* 2017 WL 4467455, at *5 ("Dr. Elliott is clearly qualified to opine on different types of vaginal mesh products after years of specializing in SUI and his other professional experiences, even though he himself does not recommend vaginal mesh. The fact that Dr. Elliott evidently does not believe that any such devices are safe does not preclude him from comparing or ranking such products."); *Herrera-Nevarez,* 2017 WL 3381718, at *7. Defendants' argument goes to the weight of the evidence, not its admissibility. *Wiltgen*, 2017 WL 4467455, at *5; *Herrera-Nevarez,* 2017 WL 3381718, at *7. Defendants' motion on this point should be denied.

IV. Dr. Elliott should be permitted to explain the unique problems associated with mechanical-cut versus laser-cut mesh.

Defendants adopt its Wave 3 argument on this issue as set forth in Section III of Doc. 2815. In response, Plaintiffs adopt is Wave 3 argument as set forth in Section IV of Doc. 2952. Additionally, the *Herrera-Nevarez* court more recently addressed Defendants' motion to exclude similar testimony concerning mechanically cut mesh versus laser cut mesh proffered by Dr. Bruce Rosenzweig, another of Plaintiff's urogynecologist experts. *Herrera-Nevarez*, 2017 WL 3381718, at *7. The court ruled that Defendants' argument went to the weight of the evidence, and not its admissibility, and denied the motion. *Id.* The Court should hold likewise here.

V. Dr. Elliott should be permitted to testify regarding Ethicon's testing and studies, in accordance with rulings in other mesh cases.

Defendants seek to exclude Dr. Elliott's opinions with respect to their testing and studies of the TVT devices. In response, Plaintiffs adopt their argument in Section V.A of Doc. 2952. Further, federal courts in remanded Ethicon mesh cases have ruled that Dr. Elliott may testify "regarding whether and why, *as a clinician*, studies and testing conducted by defendants or others are sufficient to impact his opinions regarding the TVT-O or similar devices." *Herrera-Nevarez*, 2017 WL 3381718, at *7 (emphasis in original). *See also Wiltgen*, 2017 WL 4467455, at *6 (holding same). The courts limited the testimony only to the extent it relates to the regulatory or legal adequacy of the testing. *Herrera-Nevarez*, 2017 WL 3381718, at *7; *Wiltgen*, 2017 WL 4467455, at *6.

As discussed in Section V.A of Doc. 2952, Dr. Elliott offers his disputed opinions consistent with these rulings. He does not offer the disputed testimony from the standpoint of regulatory or legal adequacy. Rather, he explains how the level of studies and tests, or lack thereof, impacted his opinions in the case. Tellingly, Ethicon conceded at the final pretrial

conference in *Herrera-Nevarez* that Dr. Elliott may testify regarding whether and why, as a clinician, studies and testing conducted by defendants or others are sufficient to impact Dr. Elliott's opinions regarding the TVT-O or similar devices. *Herrera-Nevarez*, 2017 WL 3381718, at *7. For these reasons and the reasons set forth in Doc. 2952, the Court should adopt the *Herrera-Nevarez* and *Wiltgen* rulings here, and deny Defendants' motion on this issue.

Alternatively, this Court should reserve ruling on this issue until trial, as it has previously ruled in this MDL. *In re: Ethicon, Inc. Pelvic Repair Liab. Litig*, MDL 2327, 2017 WL 1264620, at *4 (S.D. W. Va. Mar. 29, 2017) (noting that the scope of relevant testimony may vary according to state products liability law).

VI. Dr. Elliott is qualified to testify about various components and attributes of the mesh devices, including degradation, shrinkage, contraction, and cytotoxicity.

Defendants adopt its Wave 3 argument on this issue as set forth in Section V of Doc. 2815. In response, Plaintiffs adopt is Wave 3 argument as set forth in Section VI of Doc. 2952.

VII. Consistent with the Court's prior rulings, Plaintiffs will not offer Dr. Elliott to opine on Defendants' state of mind or marketing strategies, but other disputed categories of testimony in Defendants' "catchall" Section VII are relevant and admissible.

In Section VII of its brief, Defendants adopt its Wave 3 argument as set forth in Section VI of Doc. 2815, which superficially addresses a variety of topics, and also argues that opinions on cancer or other complications not suffered by a particular plaintiff should not be admitted. Plaintiffs will not offer Dr. Elliott to opine about Ethicon's state of mind or marketing strategies or merely to summarize Ethicon's documents. However, Plaintiff objects to Defendants' motion to the extent they seek to preclude Dr. Elliott from testifying as to corporate documents that support his opinions. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 722 (S.D. W. Va.

2014) (admitting expert opinions regarding complications of TVT-O surgical approach that were based on defendant's internal documents).

With respect to FDA requirements, Plaintiffs are aware that the Court has ruled that the parties may not proffer evidence regarding the FDA's 510(k) clearance process. However, consistent with the Court's prior rulings, the Court should reserve ruling on any testimony regarding design process and control standards, whether related to FDA or other requirements. *In re: Ethicon, Inc. Pelvic Repair Liab. Litig*, 2016 WL 4500768, at *5. "[T]he nuances of products liability law vary by state," and accordingly, such evidence should be evaluated in the context of applicable state law at a hearing or at trial. *Id.*

Further, Dr. Elliott's opinion testimony concerning complications not suffered by a particular plaintiff is relevant and admissible as to Plaintiffs' design defect claims. The testimony is relevant to a design defect claim, because the risk-utility analysis requires the jury to consider all known risks and complications of a device, not just those suffered by a particular plaintiff. The *Wiltgen* and *Herrera-Nevarez* courts held that Dr. Elliott's testimony on risks and complications not suffered by the plaintiff was relevant and admissible to the risk-utility test under Illinois law. *Herrera-Nevarez*, 2017 WL 3381718, at *6-8; *Wiltgen*, 2017 WL 4467455, at *7. "If all of the benefits of the product are admitted (even ones beyond those experienced by Plaintiff ...)," the *Wiltgen* court reasoned, "it only makes sense for all of the risks to be admitted as well." *Wiltgen*, 2017 WL 4467455, at *7. The same reasoning applies here, whether West Virginia or Ohio law applies, because both states use a risk-utility balancing test in design defect cases, as discussed in Section II above. Plaintiffs should thus be permitted to offer Dr. Elliott's testimony about the overall risks and benefits of the products to prove that a design defect existed.

CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully request that this Court deny Defendants' Motion to Exclude Certain General Opinions of Daniel Elliott, M.D.

Dated: March 21, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 21, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to CM/ECF participants registered to receive service in this case.

/s/ Thomas P. Cartmell